REMARKS

As of the final Office Action issued January 13, 2006, claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, 332-340, 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are pending in the present application.

Claims 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are allowed.

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 stand rejected.

No new amendments or claims are included with this response. Reconsideration of the application and an Advisory Action is respectfully requested in view of the following remarks. For the Examiner's convenience, Applicant's remarks are presented in the order in which they were raised in the Office Action.

A. Request to Rescind the Request for Continued Examination

Applicants respectfully request that upon grant of the petition to revive filed herewith, the Request for Continued Examination filed February 13, 2007 be rescinded.

B. Teleconference with Examiner M. Zeman

The applicants gratefully acknowledge and thank Examiner M. Zeman for the very helpful teleconference October 25, 2007. The applicants and Examiner M. Zeman discussed the filing of the Request for Continued Examination. The applicants and Examiner M. Zeman agreed that this response to the final Office Action dated January 13, 2006 would filed with a Petition to Revive and a request to rescind the Request for Continued Examination.

C. Allowable claims

Applicants appreciate the Examiner's determination that claims 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are allowed.

D. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description.

Specifically the Examiner alleges that the Specification, as filed, lacks support for the claim limitation of at least 12 contiguous nucleotides but less than "some arbitrary length." (Office Action at 2-3). In a telephone interview with Applicants' representative, the Examiner noted her concern with alleged lack of support for the *genus* of "at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of XXX."

Applicants respectfully traverse. The minimum and maximum lengths recited in the claims are not arbitrary but are specific lengths of polynucleotide sequences disclosed in the Specification, which also provides written description support under 35 U.S.C. § 112, first paragraph for the claim term "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of " 353, 586, 108 or 161 nucleotides as

recited in claims 60-73, 78, 81-83, 86 and 87. The remainder of the rejected claims stand rejected on the basis of their dependence from claims 60-73, 78, 81-83, 86 and 87.

A description of a genus of DNAs may be achieved by means of a recitation of a representative number of DNA sequences

Although the Federal Circuit has used various expressions to set forth the standards for compliance with *§ 112*, it is clear that the written description requirement does not require a patent applicant to provide a verbatim description of all his claims in the disclosure. *See Union Oil Co. Of Cal. v. Atl. Richfield Co ("UNOCAL"), 208 F.3d 989, 997-1001 (Fed. Cir. 2000).* Rather, "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton, 76 F.3d 1168, 1175 (Fed. Cir. 1996); see also Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)*("The test for sufficiency of support in a patent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'")(citing *Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985)).*

The written description requirement does not dictate that the applicant describe the invention exactly. Rather, what is required is that, as of the filing date, the inventor convey with reasonable clarity to those skilled in the art that the inventor was in possession of the subject matter claimed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). In order to comply with the written description requirement, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed." *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 309 F.3d 774, 779, 64 U.S.P.Q.2d 1945, 1948 (Fed. Cir. 2002) (citations omitted).

One shows that one is "in possession" of an invention by describing the invention with all its claimed limitations through "such descriptive means as words, structures, figures, diagrams,

formulas, etc., that fully set forth the claimed invention." *Hyatt v. Dudas 393 F. Supp. 2d 1 (D.C. Cir. 2005)* citing *Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).*

The Federal Circuit has addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997)

(i) Claim term: *at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of 353 nucleotides*

Claims 60, 62, 64, 66, 68, 70 and 71 specify "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in … wherein said polynucleotide has a maximum length of 353 nucleotides."

Applicants submit that while the claim term "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of 353 nucleotides" may not be explicitly recited in the Specification one of skill in the art would have understood that Applicants were in possession of the claimed invention from reviewing the Specification.[1]

Explicit support for the upper limit of "wherein said polynucleotide has a maximum length of 353 nucleotides" is found in the Specification. The complete nucleotide sequence of a 353 nucleotides long clone 81 of HCV cDNA is shown in Figure 4 and described in the Specification in section IV.C.1. Its use as a probe for identifying RNA from liver by Northern hybridization is disclosed in the Specification at page 170, line 28 – page 171 , line 19.

Explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification.

Applicants note that the Examiner has identified support for term specifying a minimum length of polynucleotide: "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-353 nucleotides.

A representative number of species encompassing the range of 12-353 nucleotides is also disclosed in the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. A 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Given the complete nucleotide sequence of a 353 bp long polynucleotide and the specific disclosure of polynucleotides encompassing 12, 15, 16, 20, 30, 80, 108, and 161 long species within the 353 long sequence, Applicants submit that one of skill in the art would understand that Applicants had possession of the genus of polynucleotides specified as: "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in … wherein said polynucleotide has a maximum length of 353 nucleotides."

(ii) Claim term: *at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of 108 nucleotides*

Claims 83, 86 and 87 specify: "[at least 12 contiguous nucleotides]… wherein said polynucleotide has a maximum length of 108 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in

[1] Applicants note that the claims are not limited to "probes" but to all polynucleotides encompassing at least 12 nucleotides of the specified sequence.

the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. The upper limit of a 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification.

Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-108 nucleotides and a representative number of species encompassing the range of 12-108 nucleotides.

(iii) Claim term: *at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of 161 nucleotides*

Claims 78, 81 and 82 specify: "[at least 12 contiguous nucleotides]… wherein said polynucleotide has a maximum length of 161 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. The upper limit of a 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-161 nucleotides and a representative number of species encompassing the range of 12-161 nucleotides.

(iv) Claim term: *at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of 586 nucleotides*

Claims 61, 63, 65, 67, 69, 71 and 73 specify "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides … wherein said polynucleotide has a maximum length of 586 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification.

Explicit support for the upper limit of "wherein said polynucleotide has a maximum length of 586 nucleotides" is found in the Specification. HCV polynucleotides 586 nucleotides in length are disclosed in section IV.C.3 and specifically at page 176, lines 34-35 of the Specification. The preparation of the 586 nucleotides long polynucleotide is disclosed at page 175, line 7 – page 176, line 35.

The complete nucleotide sequence of the 586 nucleotide long polynucleotide can be obtained from aligning the clone 36 and clone 37b primers on page 175, lines 20 and 24 of the Specification with the sequence disclosed in Figures 5, 8 and 10 of overlapping clones 35, 36 and 37b.

A representative number of species encompassing the range of 12-586 nucleotides is also disclosed in the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 also discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353

nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. A 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Nucleotide sequences of polynucleotides comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 586 nucleotides, are also disclosed in relation to the 586 base polynucleotide at page 176, lines 18-24 and 34-35 of the Specification, in Figure 5 (a polynucleotide 406 nucleotides in length), Figure 8 (a polynucleotide 480 nucleotides in length), and Figure 10 (a polynucleotide 268 nucleotides in length).

Therefore, Applicants submit that one of skill in the art would understand that Applicants had possession of the genus of polynucleotides specified as: [a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figures 1, 3, 4, 14, 26, 57, 59, 62, 72, or the nucleotide sequence in any of the viral cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394, wherein said polynucleotide has a maximum length of 586 nucleotides.

Thus, the Specification provides an adequate description of a genus of HCV DNA sequences of at least 12 and up to 108, 161, 353 and 586 nucleotides in length by identifying DNA sequences at the lower and upper limits and a representative number of DNA sequences falling within the scope of the genus and constituting a substantial portion of the genus.

Claims 76-77, 88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 depend from claims 60-73, 78, 81-83, 86 and 87 whose written description support in the specification under 35 U.S.C. § 112, first paragraph is discussed above.

Therefore Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

E. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 were rejected under 35 U.S.C. § 112, first paragraph, in the Office Action issued April 26 2007, for alleged lack of written description. To advance prosecution, applicants respectfully traverse the rejection and its supporting remarks.

The Examiner rejected the pending claims for allegedly failing to satisfy the written description requirement in the Office Action dated April 26, 2007. The Examiner cites case authority regarding the requirements for claiming a genus when an application discloses only a single or a limited number of species. Applicants respectfully submit that the cases cited are not on point. In the instant application, all of the claimed subject matter is fully described in accordance with Section 112, rendering inapplicable case law directed to the requirements for an applicant to claim a broader genus based on a limited disclosure of species.

As an initial matter, the Examiner states that "The independent claims . . . each recite polynucleotides of at least 12 contiguous nucleotides, and less than some arbitrary length, in most cases the length of the nucleic acid in the associated Figure. The specification, as filed does not provide basis for this scope of these claims." However, applicants in their July 13, 2006 Response After Final Office Action (37 C.F.R. § 1.116) have cited specific support for the upper and lower limits for the claimed polynucleotides. As defined in the specification, "the term 'polynucleotide' … refers to a polymeric form of nucleotides of any length." (Page 28, lines 19-20). Applicants in their July 13, 2006 Response cited to specific support for the 12 nucleotide lower limit, to specific polynucleotides supporting the upper limits (of 353, 108, 161, and 586 nucleotides), and to polynucleotides of lengths falling within the claimed limits. (July 13, 2006 Response at 39-45).

The Examiner further states that "The claims do not require that the polynucleotides are HCV specific." However, there is no requirement that the claims recite such a limitation. While the specification makes clear that the claimed polynucleotides have utility in, for example, detecting HCV in samples (*e.g.*, page 61, line 5 to page 64, line 2), there is no requirement in the patent laws that the utility of a claimed invention has to be recited in the claim. The Examiner also states that "There is no adequate link between structure and function for the polynucleotides encompassed by the pending claims." To the contrary, the specification plainly describes that the claimed polynucleotides can function as diagnostic oligonucleotides and probes specifically based on their structure (*i.e.*, their nucleotide sequence) and therefore can "hybridize with the HCV genome and are useful in identification of the viral agent(s), further characterization of the viral genome(s), as well as in detection of the virus(es) in diseased individuals." (Page 61, lines 9-13). Moreover, in the instant application, applicants have in fact described the structure of the claimed polynucleotides and are not relying on a description of function as a description of structure, even though such a description was held acceptable in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 966 (Fed. Cir. 2002), based on the PTO's Synopsis of Application of Written Description Guidelines. ("The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar," citing Example 9).

The present written description rejection is based on the incorrect premise that applicants are attempting to claim broad genuses of polynucleotides supported only by the description of a limited number of species. Thus, the Examiner states that "The specification provides basis for the specific HCV isolates sequenced and deposited under the recited deposit numbers. The specification does not provide for broad definitions of polynucleotides comprising at least 12 nucleotides and some amount of undisclosed sequences." In support of this rejection, the Examiner cites case law in which applicants have attempted to claim a broad genus based on the description of only a single or a limited number of species, such as in *Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567-69 (Fed. Cir. 1997), involving claims to all vertebrate or mammalian insulin cDNA when the disclosure only described a single species, rat insulin cDNA.

However, the instant claims and disclosure are completely different from those at issue in *Eli Lilly* and the other cases relied upon by the Examiner.

Applicants claimed invention is based on their discovery of the viral agent which causes Non-A, Non-B Hepatitis, now known as Hepatitis C or HCV. Applicants' discovery of HCV and their determination of its nucleotide sequence allowed for the development of, among other things, powerful diagnostic tests for determining the presence or absence of HCV in biological samples. Among these diagnostic tests are nucleic acid tests based on the HCV nucleotide sequence discovered by applicants and fully described in their application. (See Section II. H. of the specification, beginning at page 61, line 4). Applicants' specification and Figures fully describe the HCV nucleotide sequence and how polynucleotides comprising nucleotides based on the HCV sequence can be used in, for example, detecting the presence of HCV in samples.

Thus, applicants' specification clearly shows that they are in possession of polynucleotides of at least 12 contiguous nucleotides that are set forth in the referenced Figures describing nucleotide sequence information for HCV. The Examiner's written description rejection seems to be based on whether the claims encompass polynucleotides that include, in addition to at least 12 nucleotides from the referenced Figures, other "undisclosed sequences" that are not in the Figures (and which therefore are not found in, or are not complementary, to HCV). However, the claims are open to the inclusion of such additional nucleotides and one skilled in the art would recognize and understand that any such additional nucleotides, whatever they may be, are irrelevant to applicants' invention and particular contribution to the art. The claimed polynucleotides are novel, non-obvious, useful, enabled, and described based on applicants' disclosure of the HCV nucleotide sequence. One skilled in the art reading applicants' specification would readily understand that applicants were in possession of the full range of the claims because any variability created by the possible inclusion of non-HCV nucleotides beyond the required "at least 12" is not relevant to the invention.

The instant claims are therefore analogous to Example 8 of the PTO's Synopsis of Application of Written Description Guidelines, Example 8 (entitled, "DNA fragment Encoding a Full Open Reading Frame (ORF)"). In that example, a claim to a nucleotide sequence (SEQ ID NO:

2), was stated to satisfy the written description requirement even though it was interpreted to cover "a genus, i.e., any nucleic acid that minimally contains SEQ ID NO: 2" while the specification only disclosed "a single species . . . (a molecule consisting of SEQ ID NO: 2 . . .)." The example states that the written description requirement is satisfied "[a]lthough there may be substantial variability among the species of DNAs encompassed with the scope of the claim because SEQ ID NO: 2 may be combined with sequences known in the art." The example concludes that "[w]eighing all the factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2." (Synopsis of Application of Written Description Guidelines at p. 34-35.). Here, applicants' contribution is the identification of the HCV sequence and oligonucleotides comprising 12 or more nucleotides from the referenced Figures setting forth HCV sequences. One skilled in the art would readily understand that any variability introduced by the possible inclusion of other nucleotides in addition to the 12 or more nucleotides from the referenced Figures "arises due to addition of elements that are not part of the inventor's particular contribution." One skilled in the art would recognize that because the specific identification of any such additional nucleotides is irrelevant, that the instant applicants were "in possession of the genus" of polynucleotides claimed.

Moreover, each rejected claim specifically recites polynucleotides found exactly in the nucleotide sequences of specific Figures referenced in the claims. For example, claim 60 recites:

> A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of 353 nucleotides.

One skilled in the art need only look to the referenced Figures for a description of each claimed polynucleotide. Each polynucleotide within the scope of the claim is thus described so that one skilled in the art knows based on the disclosure, including the referenced Figures, precisely what is covered by the claim. Indeed, there is nothing for one skilled in the art to do other than to

read the referenced Figures, and select polynucleotides comprising from 12 to 353 contiguous nucleotides exactly as described in the Figures. The same holds for each of applicants' additional claims reciting polynucleotides of specified lengths with reference to the application's Figures. The possible inclusion of additional nucleotides not found in the referenced Figures does not negate the description of the HCV sequences encompassed by the claimed polynucleotides. One skilled in the art reading applicants' specification and Figures would instantly understand that applicants described and were in possession of the claimed polynucleotides, even if the claims were open to inclusion of additional nucleotides. Unlike in the cases relied upon by the Examiner, there are no non-described species which the applicants seek to embrace within a broad genus based on a single or limited number of described species.

Thus, the instant claims and disclosure are entirely unlike those discussed in the cases cited by the Examiner. For example, this not a case like *Eli Lilly*, 119 F.3d at 1567-69, in which the inventors attempted to claim the entire genera of cDNA encoding vertebrate and mammalian insulin sequences based on the single disclosure of cDNA encoding rat insulin. Nor is it a case like *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004) in which an applicant attempted to "claim the genus form of CD40CR antibody by simply describing mouse CD40CR." Nor is it a case like *In re Curtis*, 354 F.3d 1347, 1349 (Fed. Cir. 2004) in which the applicant argued that the disclosure in a parent application of a single species of a microcrystalline wax coating for PTFE supported a claim to a "genus of friction enhancing coatings," as later described in a CIP application. Nor is it a case like *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004), in which an applicant attempted to claim a method of selectively inhibiting an activity by administering a class of compounds without describing even a single member of that class.

In contrast to these cases, each embodiment of the instant claims is fully described in the specification and Figures. One skilled in the art reading the claims need do no more than turn to the referenced Figures to determine the sequence of each claimed polynucleotide.

In discussing the case law, the Examiner stated "For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See e.g., Eli Lilly." As made clear above,

however, the instant invention does not present such a case. All the polynucleotides within the scope of each claim are expressly described with reference to the recited Figures. Applicants are not attempting to claim "widely variant species . . by disclosing only one species within the genus." This is not a case in which applicants are attempting to generalize in an "unpredictable art" from a limited disclosure of species. Each polynucleotide within the scope of the claims is described, leaving nothing to "prediction." Moreover, applicants' method claims (*e.g.*, claims 344 to 349) are based on the well-known and *predictable* ability of polynucleotides to hybridize to complementary sequences. See *Enzo Biochem*, 323 F.3d at 966 (discussing the nucleic acid hybridization example 9 of the PTO's Synopsis of Application of Written Description Guidelines).

Finally, applicants note that the Examiner states at pages 3-4 of the Office Action dated April 26, 2007, that:

> Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species.

This language, which is a direct quote from *In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004), demonstrates that the disclosure of a protein's amino acid sequence provides written description support for each nucleic acid sequence encoding that protein.[2] However, even such a sufficient disclosure provides far less written description support than applicants' instant disclosure which provides the actual nucleic acid sequence for each claimed polynucleotide. This is not a case where the issue is whether or not the applicants have disclosed "a representative number of adequately described species" to support a genus. Here, applicants have disclosed all claimed embodiments, not merely a representative number.

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[2] Applicants note that the two cases cited by the examiner, *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382 (Fed, Cir. 1994), relate to determinations by the Federal Circuit that the prior art disclosure of a very large genus did not render obvious a claim to a species falling within the genus. Thus, in *Bell*, the Federal Circuit reversed an obviousness rejection of a claim to the nucleic acid sequences of human IGF I and II over prior art disclosing the amino acid sequences of IGF I and II, and in *Baird*, the Federal Circuit reversed an obviousness rejection of a claim to a specific bisphenol A compound over a prior art reference disclosing a genus encompassing "more than

CONCLUSION

In view of the foregoing, applicants respectfully submit that the pending claims fully satisfy the written description requirement and respectfully request withdrawal of the outstanding rejection and allowance of the claims.

Finally, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to ***Deposit Account No. 03-1952*** referencing docket no. 223002006316. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 26, 2007

Respectfully submitted,

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100 million different diphenols, only one of which is bisphenol A." Applicants respectfully submit that neither of these cases support the examiner's rejection based on written description.